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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,121	07/03/2003	Robert F. Wilson	21913-301	7183

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INSKEEP INTELLECTUAL PROPERTY GROUP, INC
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TORRANCE, CA 90504

EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/613,121

Applicant(s)

WILSON ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 7-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/04; 9/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An Election/Restriction was mailed on 16 May 2006 to applicant and was then mailed back to the USPTO as undelivered on 22 May 2006 due to an incorrect correspondence address. Applicant was notified and sent a Change of Correspondence, as well as an Associate Power of Attorney on 18 December 2006 by facsimile transmittal to note the changes on record.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to a method for reinforcing a native valve by attaching a reinforcing support, classified in class 606, subclass 151.
 - II. Claims 7-9, drawn to a delivery mechanism for a support to a valve leaflet, classified in class 606, subclass 108.
 - III. Claims 10-27, drawn to a support device, classified in class 623, subclass 2.12.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process can

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be practiced by another delivery mechanism, such as one that utilizes clips or clamps.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Inventions I and III are also related as process and apparatus for its practice. In this case, the process can be practiced by another support device, such as one that comprises biological tissue.

5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

6. Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has particulars such as a sheath and activation strings not necessitated by subcombination III, and subcombination III has particulars such as comprising barbs not necessitated by subcombination II, and they are not obvious variants of one another since they are different devices in that the function of subcombination II is to deliver a device and the function of subcombination III is to support a prolapsed valve leaflet, and also subcombination II has separate utility such as moving or opening heart valve leaflets. See MPEP § 806.05(d).

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7. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

8. Restriction to one of the following inventions is required under 35 U.S.C. 121. This application contains claims directed to the following patentably distinct species of the claimed invention.

The species for the support device are as follows:

Species 1: Figures 4 and 8 (barbs attached to downstream/upstream side)

Species 2: Figures 5,7, and 9 (support member with hinge)

Species 3: Figure 10 (support member with multiple hinges)

Species 4: Figures 11 and 12 (substrate)

Species 5: Figure 13 (network of interconnected structures)

Currently the generic claim is Claim 10.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR

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1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

12. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

13. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

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must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. During a telephone conversation with David McKinley on Tuesday, December 19, 2006 a provisional election was made without traverse to prosecute the invention of Group I directed towards Claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-27, which are directed towards Groups II and III, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Information Disclosure Statement

16. The information disclosure statements (IDS) submitted on 6 July 2004 and 14 September 2004 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by **Laufer** (U.S. Patent No. **6,083,219**).

Claims 1-6: Laufer discloses a method for treatment of damaged heart valve leaflets and for reinforcing a native valve **18** comprising attaching a reinforcing support **26, 28** to at least one valve leaflet, attaching a reinforcing support to a downstream surface of the at least one valve leaflet, as well as attaching a reinforcing support to an upstream surface of the at least one valve leaflet, or in other words, attaching a reinforcing support to both an upstream surface and a downstream surface of the at least one valve leaflet, wherein attaching a reinforcing support to both an upstream surface and a downstream surface of the at least one valve leaflet comprises sandwiching the at least one valve leaflet between adjacent support members on opposite sides of the at least one valve leaflet, or between adjacent, interlocking support members on opposite sides of the at least one valve leaflet, and said support allowing a free edge of the at least one valve leaflet to form a seal with free edges of adjacent leaflets during diastole (Figures 3-5, col. 2, lines 35-62 and col. 5, lines 8-27).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", written in a cursive style.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER